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10/018,339	12/19/2001	Hans-Peter Harz	13111-00039-US	1787
23416 7590 01/26/2007 CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207 WILMINGTON, DE 19899			EXAMINER HANLEY, SUSAN MARIE	
			ART UNIT	PAPER NUMBER
			1651	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No. 10/018,339	Applicant(s) HARZ ET AL.	
	Examiner Susan Hanley	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-17 and 19-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-17 and 19-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/23/06</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 10/23/06 has been entered.

Claims 1-4, 6-17 and 19-25 are presented for examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Claim Rejections - 35 USC § 112*

Claims 1-4, 6-17 and 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 11 and 17 are rejected because the phrase "at least one additive in an effective amount" is vague and indefinite. It is unclear what the basis for determining the metes and bound of "an effective amount" of an additive that could be anything.

### *Claim Rejections - 35 USC § 103*

Claims 1-4, 6, 8, 20 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Itoh et al. (US 5,080,917).

These claims were originally rejected over 35 USC § 102(b). In response to the amendment filed 10/23/06, the rejection is now made under 35 USC § 103. In the remarks filed 10/23/06, Applicant

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argued that Itoh does not teach the claimed coated granulate or mention its enhanced stability compared to an uncoated granulate. Applicant also argues that claim 11 now has a pelleting step and that claim 20 is dependent from claim 1 and contains all of its limitations. Applicant asserts that the Examiner made an incorrect assumption for claims 22 and 23 by assuming that the additive is the enzyme.

These arguments are addressed in the text of the following revised rejection in response to the amendment filed 10/23/06.

Itoh et al. disclose a method of making coated granules for animal feed and granules thereof, as in claims 1, 22 (method) and 24 (composition). The core may be solid and contain known binders such as PVP, hydroxypropyl cellulose or polyvinyl alcohol. This disclosure meets the limitation of a solid support. The core can also contain disintegrants such as potato or corn starch and excipients such as lactose or mannitol (col. 4, lines 19-26). In the absence of a definition by the instant specification, an additive is interpreted to mean an ingredient other than an enzyme, water and solid support material. The method of making the granulate comprises combining a binder dissolved in a suitable solvent with a suitable active substance. In Example 5, Itoh et al. disclose that the solvent was aqueous ethanol. In Comparative Test 4, Itoh et al. teach that the binder was dissolved in water. These disclosures satisfy the limitation of water as an ingredient in the granulate, as in instant claims 1 and 22. The active substance can be an enzyme such as a protease, amino acids, vitamins, sugars such as glucose or antibiotics. Itoh et al. specifically state that, "The active substances may be used either alone or in combination and mixture" (col. 2, lines 44-50), as in claims 1 and 22. The disclosure of vitamins meets the limitation of an "additive" as suggested by the instant specification on page 11. The enzyme-core granulate is prepared by conventional mechanical means which include centrifuge-fluidizing granulation (col. 4, line 68), as in instant claim 2. The granulation can produce spherical granules (col. 4, lines 52-55), as in instant claim 3. The granules are then dried to give a granulate having a diameter of about 1.4 to 3.2 mm (col.5, lines 1-10). The sequence of spherical granulation followed by drying is exemplified in Example 4, as required by instant claim 3.

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The coating taught by Itoh et al. comprises a ethyl cellulose, a high molecular weight compound which is a polymer such as methacrylate and the water-insoluble substance (claim 1 of Itoh). The high molecular weight compound comprises copolymers formed from alkyl esters of methacrylic acid and dimethylaminoethyl methacrylate. The molecular weights of the copolymers are in the rang of 50,000 to 500,000 (col. 3, lines 1-10), as in instant claim 8. It is noted that the language of the instant claims is open and that the claimed coatings can comprise other substances. The coating solution has a solids (polymer) concentration of about 1 to 10%(w/w) which overlaps the claimed concentration of 10 to 40% by weight in instant claim 8. Polyethylene glycol can be added to the coating as a plasticizer (col. 4, lines 7-10). Itoh et al. disclose that the polymeric coating can be dispersed in a non-aqueous solution (see Ex. 2 where the coating is dissolved in ethanol and acetone), as in instant claim 6. The ratio of the coating to the granule core is at a weight ratio of 5-100 parts of the coating agent per 100 parts core (col. 4, lines 30-40). Thus, in a coated granule, the percent weight ratio of the coating agent is about 2.5 to 50%, as in claim 23. The diameter of the granule is in the range of 0.5 to 3.0 mm (col. 5, lines 1-10).

Claim 20 is drawn to an organic polymer that is filler-free. According to the MPEP 2111, during patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." In re Hyatt, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (discussed below); *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1372, 69 USPQ2d 1857 (Fed. Cir. 2004). According to Webster's Dictionary a filler is defined as "something added to augment weight, size or space" (p. 487). The coating taught by Itoh et al. comprises a ethyl cellulose, a high molecular weight compound which is a polymer such as methacrylate and the water-insoluble substance (claim 1 of Itoh). The purpose of the water-insoluble compound is to form a stronger coating layer (col. 3, lines 36-46). Therefore, the limitation of instant claim 20 is met by Itoh because none of the components meet the definition of a filler.

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Itoh et al. disclose examples for making coated granulates that are batch methods, as in instant claim 4.

Itoh et al. do not specifically exemplify an enzyme-containing granulate that is suitable for animal feed. Nor does Itoh specifically state that the organic-polymer-coated enzyme-containing granulate has a pelleting stability greater than uncoated enzyme-containing granules.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a coated enzyme-containing granulate wherein the coating comprises an organic polymer. The ordinary artisan would have been motivated to do so because Itoh et al. specifically suggest that the coated granulate contain a physiologically active substance which is an enzyme such as a protease (col. 2, lines 49-50). The protease is a specie in a small genus of active substances taught by Itoh et al. (see col. 2, lines 43-55). Therefore, the ordinary artisan could easily envisage an enzyme-containing granulate that is coated by an organic polymer. The ordinary artisan would have had a reasonable expectation that he or she could make and use an enzyme-containing granulate coated by an organic polymer because Itoh et al. provide examples of making granulates with biologically active substances under conditions that the ordinary artisan would expect an enzyme to survive intact.

It would have been obvious to one of ordinary skill in the art at the time the invention was made that the organic-polymer-coated enzyme-containing granulate would have had a pelleting stability greater than uncoated enzyme-containing granules. As noted supra, the MPEP 2111, notes that during patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." In re Hyatt, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (discussed below); *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1372, 69 USPQ2d 1857 (Fed. Cir. 2004). In the instant case, the specification does not provide as specific definition for "pelleting stability." Thus, "pelleting stability" is interpreted to mean the ability of the active substance in the coated

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granulate to maintain its activity after pelletizing of the granulate. It is noted that independent claims 1 and 22 do not actually have a pelleting step. Hence, the phrase "wherein the enzyme-containing granulate has a pelleting stability greater than uncoated granulates" refers to a property that is conferred to the granulates because of the coating process. It is noted on pages 20-21 of the specification that one method of determining pelleting stability is to determine the activity of the enzyme after the granulate has been pelleted.

Itoh et al. teaches that it is desirous to inhibit decomposition of a granulate in the first cow stomach in the digestive system in order to maintain the activity of the biologically active substance in the remaining cow stomachs. Thus, the disclosed coating protects the active substance in the granulate (col. 1, lines 1-31). Itoh et al. measured the stability afforded by the organic polymer coating by feeding cows granulates having a) no methionine; b) having methionine and uncoated; and c) having methionine and coated. The concentration of methionine in blood was determined. The results in Table 4 demonstrate that the granulates supplemented by the organic polymer coating were better able to survive the acidic digestive tract of the cow. Thus, Itoh performs that same process as the instant claims to make enzyme-containing granulates that are coated by an organic polymer. Itoh demonstrates that the organic polymer is directly responsible for preserving the activity of the amino acid contained in the coated granulate. Therefore, the claims are drawn to a method for making an enzyme-containing granulate having a coating comprising an organic polymer. The method is reasonably interpreted as granulating a mixture comprising a solid support, enzyme, water and an additive to produce a granulate, drying the granulate and coating it with a composition containing an organic polymer. The reference shows the same physical steps: granulating an active substance that is an enzyme (based on obviousness), a solvent that can be water, a binder (solid support) and an additive (vitamin, amino acid, etc.); drying the granulate and then coating the granulate with a coating that contains an organic polymer that can be a methacrylate. Itoh et al. demonstrate that the coating stabilizes the active substance in the core. Thus, the ordinary artisan would have had a reasonable expectation that the coated granulate made by Itoh et al. would have

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comparable pelleting stability because Itoh et al. make a coated granulate using the same physical steps, as claimed, and demonstrate that the coating imparts stability to the active substance in the coated granulate.

Regarding Applicant's argument that Itoh et al. do not recognize that the organic coating would improve the pelleting stability, Itoh et al. do recognize the stability imparted by the coating to the active substance, see Ex. 4. Further, there is no requirement that a person of ordinary skill in the art would have recognized the improved pelleting stability imparted by the coating at the time of invention. Such stability is a property that flows from the physical steps of the process.

Claims 1-4, 6-17 and 19-23 stand provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 10/125,272 which has a common assignee with the instant application.

Applicant asserts that an appropriate terminal disclaimer will be filed in the event that the instant application becomes allowable.

Claims 1-4, 6-17 and 19-23 stand provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 10/280,324 which has a common assignee with the instant application in view of Itoh et al. US 5,080,917.

Applicant argues that neither the '324 application nor Itoh, alone or together, teach or suggest the method of claim 1. Applicant asserts that the motivation cited by the Examiner (coating granules to protect them from acidic degradation in the stomach of an animal) does not teach or suggest that an organic-polymer coating would improve the pelleting stability of an enzyme-containing granulate compared to an uncoated granulate. Applicant asserts that the Examiner has acknowledged that Itoh does not teach a pellet comprising a polymer-coated enzyme-containing granule.



In response to applicant's argument that Itoh does not provide motivation for coating granulates in order to improve their pelleting stability, *per se*, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Thus, the ordinary artisan would have had a reasonable expectation that the coated granulate made by Itoh et al. would have comparable pelleting stability because Itoh et al. make a coated granulate using the same physical steps, as claimed, and demonstrate that the coating imparts stability to the active substance in the coated granulate.

Regarding Applicant's argument that Itoh et al. do not recognize that the organic coating would improve the pelleting stability, Itoh et al. do recognize the stability imparted by the coating to the active substance, see Ex. 4. Further, there is no requirement that a person of ordinary skill in the art would have recognized the improved pelleting stability imparted by the coating at the time of invention. Such stability is a property that flows from the physical steps of the process.

Claims 1-4, 6, 8-17, and 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Itoh et al. (US 5,080,917), as applied to claims 1-4, 6, 8, 20, and 22-24, in further view of Johnson et al. (US 4,976,977) and Jacobsen (US 5,391,371).

Applicant argues that Johnson teaches the pelleting of clay particles for animal feed. Applicant asserts that Johnson does not suggest or teach a pellet comprising a polymer-coated enzyme-containing granulate. Applicant argues that Jacobson was discussed in the instant specification as having a totally different method for coating T-granulates which require a high content of organic filler and a complex multi-stage coating of a specialized support. Applicant further argues that none of the references together or separately teach the instant invention.

Responding to Applicant's argument regarding the appropriateness of the supporting references, Johnson and Jacobson refer to problems that are applicable to all types of feed that are comprised of

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granulates. Johnson teaches that it is desirable to pellet particulate matter intended as an animal feed because these materials are finely divided and difficult-to-handle. Pelletizing using heat, moisture and pressure to make larger pelletized material. The diameter of a granulate made by Itoh et al. is on the order of 0.5 to 3.0 mm (col. 5, lines 1-10). Granulates of this size are finely divided and difficult to handle. Thus, the motivation to pellet a granulate is rooted in the size and not the type of granulate.

Similarly, Jacobson speaks to problems common to pelletized enzyme-containing granulates that are intended for fodder. Pelletizing any type of granulate takes heat which is detrimental to most enzymes (col. 1, lines 10-30). Thus, stabilization of the coating of the granulate is a problem for any type of granulate. Furthermore, Itoh et al. recognized that PEG is a useful additive for the organic coating mixture because it is a plasticizer (col. 4, lines 7-10). Thus, Itoh and Johnson have common ground in the recognition that stabilization of the coating imparts stabilization to the granulate.

#### *Double Patenting*

Claims 1-4, 7, 10-16, 19, 20, 22 and 23 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-8 and 14-19 of copending Application No. 10/125,272, now allowed.

Applicant asserts that an appropriate terminal disclaimer will be filed in the event that the instant application becomes allowable.

Claims 1-4, 11-17, 22, 24 and 25 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 8, 9, 11-21, 26-28, 31, 32, 34, 36, 37, 39-41, 43, and 45-50 of copending Application No. 10/280,324 in view of Itoh et al. (US 5,080,917).

Applicant argues that Itoh does not teach or suggest the limitation of instant claims 1-4 "which are related to the production of the granulate" and that there is no prima facie case made to justify

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obviousness because it is not clear what steps in the recited process are related to the production of a granulate.

The rejection is restated as follows:

Claims 1, 26, 27, 39 and 48 of '324 are drawn to a process for preparing a phosphatase-containing granule suitable for animal feed comprising the steps of mixing a solid carrier comprising starch with water and phosphatase to make a granule that is then dried. These claims correspond to instant claims 1, 11, 17 and 22 because they comprise the same steps, with the exception of a coating step. The phytase is a specie that anticipates the enzyme genus that is instantly claimed. Claims 2-4, 9, 15, 18, 31, 36, 40, 43, 45, and 49 further describe the phytase specie. Claim 5 of '324 is analogous to the granulation methods of instant claim 2. Claim 6 relates to the order of mixing as is a specie of instant claim 1. Claim 8 of '324 is analogous to instant claim 3. Claims 11-14 of '324 correspond to the additive or solid support of the granules of instant claims 1, 11, 17 and 22. Claims 16, 19, 20 and 23 are drawn to a feed that contains the granulate that is a specie of a composition that comprises (open language) a granulate, as in instant claims 1, 11, 17 and 22. Claims 17, 21, and 28 of '324 are drawn to pelleting the granulate, as in instant claims 11, 17 and 25. Claims 32, 34, 37, 41, 46, and 50 are drawn to coating the granulate, as in instant claims 1, 11, 17 and 22.

The claims of '324 do not teach coating the enzyme-containing granulate with an organic polymer such as a methacrylate such that the pelleting stability of the coated granulate is greater than that of the uncoated granulate.

The disclosure of Ito is discussed *supra*.

It would have been obvious to one of ordinary skill at the time the invention was made to coat the enzyme-containing granulate claimed in '324 with an organic polymer such as a methacrylate such that the pelleting stability of the coated granulate is greater than that of the uncoated granulate. The ordinary artisan would have been motivated to do so because such a coating serves to protect the enzyme from acidic degradation in the stomach of the animal. Hence, more of the enzyme would survive the first

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pass effect and would be available to cause the desired therapeutic effect in the animal. The ordinary artisan would have had a reasonable expectation that an enzyme-containing granule could be successfully coated by a polymer and subsequently be used as animal feed because Itoh et al. teaches that polymer-coated enzyme-containing granules are well known in the art and that their invention is merely an improvement on well known technology.

Although Itoh et al. do not explicitly recognize that the organic coating would improve the pelleting stability of the granulate, Itoh et al. do recognize the stability imparted by the coating to the active substance, see Ex. 4. Further, there is no requirement that a person of ordinary skill in the art would have recognized the improved pelleting stability imparted by the coating at the time of invention. Such stability is a property that flows from the physical steps of the process. Thus, the ordinary artisan would have had a reasonable expectation that coating the enzyme-containing granulate of '324 by the method of Itoh et al. would have improved pelleting stability compared to an uncoated granulate because Itoh et al. make a coated granulate using the same physical steps, as claimed, and demonstrate that the coating imparts stability to the active substance in the coated granulate.

This is a provisional obviousness-type double patenting rejection.

Claims 1-4, 6, 22 and 23 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5, 8, 12, 13 and 16 of copending Application No. 10/500,144 in view of Itoh (US 5,080,917).

Applicant argues that Itoh does not teach or suggest the limitation of instant claims 1-4 "which are related to the production of the granulate" and that there is no prima facie case made to justify obviousness because it is not clear what steps in the recited process are related to the production of a granulate.

The rejection is restated as follows:

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Claim 1 of '144 is drawn to a method for preparing an enzyme-containing granulate suitable for use in animal feed comprising obtaining a dry enzyme-containing granulate and coating the granulate with a polyolefin. This claimed subject matter corresponds to instant claims 1 and 22 with the exception of claiming the mixing together of the enzyme, an additive and water to make a granulate that is then dried. Claims 2, 3 and 8 of '144 are further drawn to the specie of the polymer coating. Claim 5 of '144 is drawn to the application of the coating as a dispersion which is analogous to instant claim 6. Claim 12 of '144 claims specific enzymes that are species of the enzyme genus of claims 1 and 22. Claims 13 and 16 of '144 relate to a granulate or feed containing a granulate which are analogous to instant claim 24. Instant claim 24 has open language (comprising). Thus, the addition of other feed ingredients still reads on instant claim 24.

As noted *supra*, '144 does not claim the mixing together of the enzyme, an additive and water to make a granulate that is then dried. Nor does the claims of '144 teach that the coated enzyme-containing granulate has a pelleting stability greater than that of the uncoated enzyme-containing granulate.

The disclosure of Ito is discussed *supra*.

It would have been obvious to one of ordinary skill at the time the invention was made to prepare the enzyme-containing granulate claimed in '144 by the conventional method of Ito et al. such that the pelleting stability of the coated granulate is greater than that of the uncoated granulate. The ordinary artisan would have been motivated to make the enzyme-containing granulate by the method of Ito et al. because such methods are well known in the art of granulate-making, as exemplified by Ito et al. The ordinary artisan would have had a reasonable expectation that conventional granulation preparation methods would successfully guide the ordinary artisan in making a suitable granulate recited in the claims of '144 because the examples provided by Ito et al. provide clear examples of a well known process.

Although Itoh et al. do not explicitly recognize that the organic coating would improve the pelleting stability of the granulate, Itoh et al. do recognize the stability imparted by the coating to the

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active substance, see Ex. 4. Further, there is no requirement that a person of ordinary skill in the art would have recognized the improved pelleting stability imparted by the coating at the time of invention. Such stability is a property that flows from the physical steps of the process. Thus, the ordinary artisan would have had a reasonable expectation that a coated enzyme-containing granulate of '144 having the enzyme-containing granulate prepared by the method of Itoh et al. would have improved pelleting stability compared to an uncoated granulate because the combined method of Itoh et al. and the claims of '144 to make a coated enzyme-containing granulate uses the same physical steps, as claimed, and the ordinary artisan would have a reasonable expectation that said coated enzyme-containing granulate would have the same properties.

This is a provisional obviousness-type double patenting rejection.

Claims 1-4, 8-17 and 19 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2 and 4 of U.S. Patent No. 6,500,426 in view of Itoh (US 5,080,917).

Applicant argues that the claims have been amended to make them analogous to co-pending 10/125,272. Applicant asserts that the BPAI decision, Appeal No. 2006-0201, found that the claims of 10/125,272 were allegedly non-obvious nor anticipated by the '426 patent (WO98/54980). Applicant argues that Itoh does not teach or suggest the method of claim 1. Applicant asserts that the motivation cited by the Examiner (coating granules to protect them from acidic degradation in the stomach of an animal) does not teach or suggest that an organic-polymer coating would improve the stability of an enzyme-containing granulate compared to an uncoated granulate. Applicant also points out that independent claims 11 and 17 were not included in the rejection even though the claims depending therefrom (12-16 and 19) were included in the rejection.

Responding to Applicant's argument that the amending of the instant claims such that they are now similar to co-pending application No. 10/125,272, this argument is not found persuasive because

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each application is examined on its own merits. Regarding Applicant's assertion that BPAI found WO98/54980 (the '426 patent) as neither anticipatory nor obvious over the invention of '272, during the prosecution of 10/125,272, the international application WO98/54980 was combined with a reference that is not cited in this Office action for any rejection. A rejection must be evaluated by all of the references applied and arguments made thereto. Responding to Applicant's argument that Itoh does not teach the method of claim 1, it is not required that a supporting reference be anticipatory to an independent claim in order to apply it in an obviousness rejection.

In response to applicant's argument that Itoh does not provide motivation for coating granulates in order to improve their stability, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Regarding the claimed improved stability, Itoh teaches that his coated granulates have greater stability compared to non-coated granulates because the coated granulates are stable to acid-breakdown in an animal's stomach. The oversight of not including claims 11 and 17 in the claims has been corrected.

No claim is allowed.

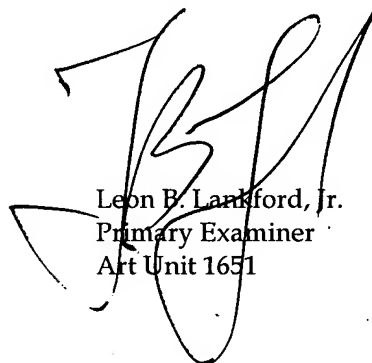
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Susan Hanley  
Patent Examiner  
AU 1651



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